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Kevin E. Noonan McDonnell Boehnen Hulbert & Berghoff 32nd Floor 300 S. Wacker Drive Chicago, IL 60606				
EXAMINER				
SOROUSH, LAYLA				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Continuation Sheet:

Applicant argues that they have limited their claims to wounds to the dermis/epidermis, terms the skilled worker would understand do not encompass ophthalmic injuries. Examiner respectfully reiterates that Bankneider created a wound in diabetic animal models, treated the animals with controls, regular diet and tolerstat doses and subsequently determined that rats that were treated with had improved wound healing (see entire col 2-3; claims 1-5). The wounds created by Bankneider is on the skin and thus on the dermis or epidermis of the subjects. Accordingly, the limitation of treating wounds to the dermis/epidermis is met by the prior art reference. Therefore, Applicant's arguments are not found persuasive.

Additionally, in response to Applicants argument that the method of identifying an aldose reductase inhibitor for topical administration to facilitate wound healing in a diabetic animal was not obvious in light of systemic use of ARI is not persuasive. Examiner points to York where the equivalence of topical and systemic delivery is taught. More specifically, York teaches in the background of the invention "these aldose reductase inhibitors can be applied topically to the eye or systemically to the diabetic to promote wound healing when indicated (col. 1 lines 35-40)." Examiner also, respectfully reiterates that York shows aldose reductase inhibitors are also suitable and effective in treatment through carrier systems appropriate for topical and ocular administration in humans. (see abstract, col 1, lines 25-59; col 2, lines 1-67).

Applicant argues that the skilled artisan would not have been motivated to consider the cited art directed to aldose reductase inhibitor compounds (ARIs) known

and used for systemic administration for treating wounds or ophthalmic injuries for treating wounds topically; specifically, this art would not have motivated the skilled worker to treat skin wounds created by punch biopsy to be measured by rate intervals of wound healing. Examiner reiterates the York reference teaches the equivalence of topical and systemic delivery. Further, Depiro et al. is used to show that it is well within the purview of one of ordinary skill in the art to prepare a topical or ophthalmic formulation, once in possession of the active ingredient. (see p 42-45, specifically sections under biopharmaceutical and therapeutic considerations). Accordingly, converting a ophthalmic to a topical composition is a matter of optimizing the carrier system.

Thus, it would have been also obvious to one of ordinary skill in the art at the time of invention to practice Banknieder's method by administering his aldose reductase inhibitor topically to a site of interest on the skin, because as shown by York, such compounds as aldose reductase inhibitors, can provide their wound healing properties when administered topically. A person of ordinary skill in the art would have had a reasonable expectation of success because, as described by York, aldose reductase inhibitors provide their wound healing effects when administered topically.

Applicant argues that the reference is also devoid of any teaching related to punch biopsy to produce a wound. It is the Examiners position that the mechanism of producing a wound is irrelevant to the actual invention -- "a method of identifying a compound that improves treatment of wounds to dermis or epidermis in a diabetic animal." Additionally, it would have been obvious to one of ordinary skill in the art at the

time of invention to treat a wound in respective studied subjects by any known mechanism of producing a wound, such as punch biopsy, because the ordinary skill in the art would have expected to see the same results in any type of skin wound created on the skin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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